

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

U.S. DISTRICT COURT
DISTRICT OF VERMONT
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JACINTA LEAVITT and PAUL LEAVITT,)
)
Plaintiffs,)
)
v.)
)
ETHICON, INC., and)
JOHNSON & JOHNSON,)
)
Defendants.)

Case No. 2:20-cv-00176

**OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO LIMIT
EXPERT TESTIMONY AND GRANTING PLAINTIFFS' MOTION TO LIMIT
EXPERT TESTIMONY**
(Docs. 30 & 32)

This case arises out of alleged injuries suffered by Plaintiff Jacinta Leavitt ("Plaintiff J. Leavitt") following the implantation of tension-free vaginal tape ("TVT") for the treatment of her stress urinary incontinence. Plaintiff Paul Leavitt ("Plaintiff P. Leavitt") is Plaintiff J. Leavitt's husband. Plaintiffs assert negligence, strict liability for failure to warn, strict liability for design defect, negligent infliction of emotional distress, gross negligence, loss of consortium, and punitive damages claims against Defendants.

Pending before the court is Defendants' motion to exclude certain opinions and testimony of Plaintiffs' expert witness Donald Ostergard, MD, (Doc. 30), and Plaintiffs' motion to exclude certain opinions and testimony of Defendants' expert witness Lawrence Lind, MD. (Doc. 32.) Oral argument was held on June 9, 2021, after which the court took the pending motions under advisement. With regard to Dr. Ostergard, in the course of oral argument, the court ruled on the record that provided Dr. Ostergard testifies about the foundation for his opinions, he is qualified to testify that the TVT caused Plaintiff J. Leavitt's dyspareunia and pelvic floor muscle tenderness and spasm.

Plaintiffs are represented by D. Michael Noonan, Esq., Kenneth J. Brennan, Esq., Maxwell S. Kennerly, Esq., Steven D. Davis, Esq., and Tyler J. Schneider, Esq.

Defendants are represented by James M. Campbell, Esq., and Kathleen M. Guilfoyle, Esq.

I. Conclusions of Law and Analysis.

A. Standard of Review.

Under Federal Rule of Evidence 702:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

The district court functions as the gatekeeper for expert testimony, ensuring “that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.”

Amorgianos v. Nat’l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)).

In determining the reliability of expert testimony, the court engages in “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592-93. Under *Daubert* and its progeny, relevant factors include the theory’s verifiability, the extent to which it “has been subjected to peer review and publication[,]” the extent to which a technique is subject to “standards controlling the technique’s operation,” the “known or potential rate of error,” and the “degree of acceptance” within the relevant scientific community.” *Id.* at 593-94. “[T]he test of reliability is ‘flexible,’ and *Daubert*’s list of specific factors neither necessarily nor exclusively applies to all experts or in every case.” *Restivo v. Hessemann*,

846 F.3d 547, 576 (2d Cir. 2017), *cert. denied*, 138 S. Ct. 644 (2018) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999)).

“[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.” *Amorgianos*, 303 F.3d at 266. The court has the same “broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination.” *Kumho Tire Co.*, 526 U.S. at 142 (emphasis in original); *see also Restivo*, 846 F.3d at 575 (“Thus, in analyzing the admissibility of expert evidence, the district court has broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case.”) (internal quotation marks omitted).

Admissible testimony under Rule 702 may still be excluded under Federal Rule of Evidence 403, when its “probative value is substantially outweighed by [the] danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. “Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.” *Daubert*, 509 U.S. at 595 (internal quotation marks omitted).

B. Whether to Grant Defendants’ Motion to Limit Opinions of Dr. Ostergard.

Defendants assert that the following case-specific opinions of Donald Ostergard, MD, should be excluded because they are unreliable, irrelevant, unhelpful, and otherwise inadmissible: (1) opinions regarding complications not experienced by Plaintiff J. Leavitt; (2) opinions concerning the cause of Plaintiff J. Leavitt’s alleged injuries; and (3) opinions regarding safer alternative designs, treatments, and procedures.¹

¹ At the hearing on the motion, the parties agreed that Dr. Ostergard would not opine that Defendants’ product was defective, would not discuss informed consent, and would not testify about the Instructions for Use.

1. Opinions and Testimony Regarding Complications Not Experienced by Plaintiff J. Leavitt.

In the section of his report labeled “Future Possible Adverse Events[.]” Dr. Ostergard opines, to a reasonable degree of medical probability, that “[s]ince most of the implanted Ethicon [] TVT pubourethral sling mesh remains in the dense fibrotic tissue produced by the device in [Plaintiff J.] Leavitt’s body, the potential exists for . . . cancer associated with the mesh and infection for as long as the mesh remains in her body[.]” (Doc. 30-1 at 20-21, ¶ 81.)

Defendants argue that Dr. Ostergard’s opinion that complete removal of the TVT is “not possible due to the degradation of the polypropylene which weakens the mesh to the point that it literally falls apart[.]” *id.* at 5, as well as his testimony regarding the possibility that Plaintiff J. Leavitt may develop cancer or an infection as a result of complications from her residual TVT, should be excluded because the TVT has been removed and no longer poses a risk² and, even if it does, any remaining risk is speculative. Plaintiffs counter that Dr. Ostergard is well-qualified to discuss potential risks associated with TVT, including whether the TVT “mesh that remains in her might degrade, and that such degradation could cause injury.” (Doc. 39 at 8.)

Although Dr. Ostergard opines that removal of the TVT is not possible due to degradation, he also opines that it is unknown whether Plaintiff J. Leavitt’s TVT has degraded. *See* Doc. 30-1 at 18, ¶ 73 (listing “degradation of the device” as unknown). His opinions regarding degradation are thus not based on the facts of this case, and he offers no specific opinion relevant to Plaintiff J. Leavitt’s own risks because of TVT degradation. In this respect, his opinion is not case-specific and is not helpful in evaluating the risks Plaintiff J. Leavitt is reasonably likely to face in the future. *See Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 81 (2d Cir. 1997) (“In admitting expert testimony, a trial court must determine whether the expert’s reasoning and methodology can appropriately be applied to the facts of the case before it.”). For this reason, Dr. Ostergard

² At oral argument, Defendants acknowledged that whether some portion of the TVT remained was contested.

shall not opine that Plaintiff J. Leavitt's TVT has degraded. *See Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006) ("Expert testimony is inadmissible if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case.").

Dr. Ostergard's opinion that Plaintiff J. Leavitt's residual TVT could cause cancer, infection, and other complications not experienced by Plaintiff J. Leavitt is also not case-specific because Dr. Ostergard does not opine that it is more likely than not that Plaintiff J. Leavitt will develop future complications or that Plaintiff J. Leavitt is at a specific increased risk for developing any of the complications identified. Any expert testimony about such complications is thus speculative. As a result, Dr. Ostergard's opinions regarding future complications not experienced by Plaintiff J. Leavitt must be excluded. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 553 (S.D.W. Va. 2014) (concluding that "[a]lthough the plaintiffs point to several studies connecting polypropylene to cancer, . . . none of the plaintiffs in this case have claimed that the . . . sling caused cancer. Thus, [t]he mention of cancer in the context of this case . . . would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value") (internal quotation marks and citation omitted) (second alteration in original); *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at *7 (S.D.W. Va. Feb. 7, 2015) (holding that because the plaintiff "has not claimed that the [mesh] caused cancer, . . . the mention of cancer in the context of this case would, at a minimum, offend Federal Rule of Evidence 702 and confuse the jury on a matter with scant probative value"); *Balura v. Ethicon, Inc.*, 2020 WL 819293, at *10 (N.D.N.Y. Feb. 19, 2020) (excluding expert testimony about future complications not experienced by the plaintiff because the expert failed to explain "why he believes that it is more likely than not that" the plaintiff will develop certain complications); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, at *5 (S.D.W. Va. Aug. 26, 2016) (limiting the plaintiff's expert witness testimony because "[e]vidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value").

For the foregoing reasons, Defendants' motion to exclude Dr. Ostergard's opinions that Plaintiff J. Leavitt's TVT has degraded and that the residual TVT mesh

placed Plaintiff J. Leavitt at an increased risk of developing certain complications she has not experienced is GRANTED.

2. Opinions and Testimony Regarding Defendant Ethicon's Warnings.

Defendants contend that Dr. Ostergard's opinions regarding Defendant Ethicon's failure to warn Plaintiffs of the harms associated with TVT in the patient brochure should be excluded because he did not disclose any such opinion in his expert report.³ The court agrees.

An expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them[]" and an expert witness has an affirmative duty to supplement his or her report "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing[.]" Fed. R. Civ. P. 26(a)(2)(B)(i), (e)(1)(A).

Because "a party [that] fails to provide information . . . as required by Rule 26(a) or (e) . . . is not allowed to use that information . . . at a trial, unless the failure was substantially justified or is harmless[.]" Fed. R. Civ. P. 37(c)(1), and because Plaintiffs provide no reasons for failing to disclose such information, Defendants' motion to exclude Dr. Ostergard's opinion regarding the warnings in the patient brochure is GRANTED.

3. Opinions and Testimony Regarding Safer Alternative Treatments and Procedures.

Dr. Ostergard opines that:

The use of a safer product for the treatment of stress incontinence by surgery, medical treatment or devices: large-pore mesh, continence pessary, Kegel's exercises, behavioral modifications (weight, fluid consumption

³ At oral argument, Plaintiffs could not identify where in Dr. Ostergard's expert report he opines that warnings in the patient brochure are inadequate. The court gave Plaintiffs until June 11, 2021 to supply such information; Plaintiffs did not provide the court with any additional information by that date.

amount and type, timed voidings), tampon or diaphragm insertion, electrical stimulation, estrogen vaginal crème, biofeedback, vaginal cones, radiofrequency denaturation, stem cell injections, fibrin sealant, Kelly urethrocytostocle plication, pubovaginal sling using cadaveric or autologous fascia or a similar biological product, Burch procedure, MMK procedure, Raz, Pereyra, Stamey or Gittes needle suspension orintraurethral bulking agent injection may have eliminated the risks associated with the defects inherent in this flawed device, including chronic inflammation, degradation, shrinkage, and infection.

(Doc. 30-1 at 21, ¶ 82.)

Defendants argue that Dr. Ostergard should be precluded from opining that certain non-mesh procedures, including non-surgical treatment options, are safer alternatives to TVT mesh. They point to the MDL court’s ruling that alternative non-mesh surgical procedures “do not inform the issue of whether an alternative design for a [surgical mesh] product exists.” (Doc. 31 at 9.) (internal quotation marks omitted). Defendants also contend that Dr. Ostergard’s opinion that large-pore mesh is a safer alternative product should be excluded as that product was unavailable to Defendant Ethicon as an alternative at the time of Plaintiff J. Leavitt’s surgery because the product failed Food and Drug Administration (“FDA”) tests.

Dr. Ostergard’s opinion that non-surgical alternatives are safer than Defendant Ethicon’s TVT is not relevant to determining whether there was a safer alternative design because “[w]hether an alternative procedure could have been p[er]formed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible design for the TVT.” *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D.W. Va. 2017) (emphasis omitted).⁴ In other words, a safer alternative treatment or procedure that

⁴ See also *Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) (holding that determining whether an alternative procedure or surgery was safer “is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product”); *Hosbrook v. Ethicon, Inc.*, 2021 WL 1599199, at *3-4 (S.D. Ohio April 23, 2021) (excluding expert testimony regarding “alternative traditional surgical procedures” because “[a]lthough [p]laintiff may be correct that [the] four procedures are intended to merely inform the jury that biologic grafts are safer than Prolift, the fact remains that Prolift is a product and [p]laintiff must establish under the TPLA that it was ‘in a defective condition’ or ‘unreasonably dangerous’”) (applying Tennessee Products Liability Act).

does not include a safer alternative design of the product in question yields no relevant information regarding whether a safer alternative design was feasible. Dr. Ostergard's opinions that non-surgical alternatives are safer than TVT must be excluded because they are unhelpful and are likely to confuse the jury regarding the proper issue to be decided. *See* Fed. R. Evid. 702(a); *Hosbrook v. Ethicon, Inc.*, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021) ("To introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury.").

Dr. Ostergard provides no basis for his further opinion that large-pore mesh is a safer alternative, nor does he address whether a large-pore mesh was an available, feasible alternative at the time of Plaintiff J. Leavitt's surgery. He opines only that the TVT is a "polypropylene mesh [that] is heavy weight, small pore, impure, not inert, degrades, shrinks, causes chronic inflammation[,] dense fibrosis[,] and potentiates infection[]" and that "[t]he use of a safer product" including "large-pore mesh . . . may have eliminated the risks associated with the defects inherent in this flawed device[.]" (Doc. 30-1 at 21, ¶ 82.) In rendering this opinion, Dr. Ostergard does not rely on "peer-reviewed studies, scientific or testing evidence, or any principles or methodology[.]" *Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 902 (S.D. Iowa 2020), to support his conclusion. Instead, he appears to rely on evidence that purports to demonstrate the shortcomings of small-pore mesh to show the inverse is true, that large-pore mesh is safer. This is an insufficient basis for an expert opinion. *See id.* at 909 (excluding testimony regarding large-pore mesh because an expert witness "simply leaps from the problems with the [mesh] to the conclusion that the [large-pore mesh] would be safer, without adequate support"); Fed. R. Evid. 702(b)-(c) (stating that an expert may testify if "the testimony is based on sufficient facts or data[]" and "is the product of reliable principles and methods"). It also ignores Defendants' unrebutted contention that TVT constructed with large-pore mesh such as Ultrapro was not available at the time of Plaintiff J. Leavitt's TVT implantation surgery.

For the foregoing reasons, Defendants' motion to exclude Dr. Ostergard's opinions regarding safer alternative treatments, procedures, or designs is GRANTED.

C. Whether to Grant Plaintiffs' Motion to Limit Dr. Lind's Opinions Regarding Plaintiff J. Leavitt's Mental Health.

With regard to Dr. Lind's opinions, the only issue before the court is whether to limit his testimony regarding Plaintiff J. Leavitt's mental health. Plaintiffs assert that Dr. Lind is not qualified to opine on Plaintiff J. Leavitt's mental health and that his differential diagnosis should be excluded. Defendants respond that Dr. Lind states only that Plaintiff J. Leavitt's TVT did not cause her mental health symptoms, including anxiety, depression, and post-traumatic stress disorder ("PTSD"). They contend that he is qualified to render these opinions because a physician need not specialize in mental health in order to provide an opinion about it.

Dr. Lind opines that:

It is my opinion that [Plaintiff J.] Leavitt's anxiety, depression and PTSD, which she blames on the TVT, have been caused by traumatic experiences in her life that are well documented in the medical records to have caused her to seek mental health treatment. [Plaintiff J.] Leavitt's records document 4-5 years of psychologic care prior to the TVT procedure[.]

The patient repeatedly attributed her emotional problems to difficulties dealing with and/or facing the impact of childhood sexual abuse. She also repeatedly attributed emotional problems to her emergency surgery and 'near death experience' related to her ectopic pregnancy as well as the death of her family member. There is a well-established record of severe emotional and psychologic disabilities which antedate the TVT and are attributed by the patient to other causes. These conditions were not caused by the TVT.

(Doc. 32-1 at 39-40.)

If an "expert has educational and experiential qualifications in a general field *closely related* to the subject matter in question, the court will not exclude [an expert's] testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." *Davids v. Novartis Pharms. Corp.*, 857 F. Supp. 2d 267, 277 (E.D.N.Y. 2012) (emphasis supplied) (quoting *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007)) (internal quotation marks omitted).

In *Tardif v. City of New York*, 344 F. Supp. 3d 579, 598 (S.D.N.Y. 2018), the defendants argued that an expert witness was not qualified to render opinions regarding

PTSD, depression, and anxiety disorder because he was not an expert on those disorders. However, because the expert witness had received an advanced academic degree in psychology and had treated individuals with PTSD for at least a year, the court found him qualified to render an opinion on the plaintiff's mental health. Similarly, in *Monterey v. City of New York*, 2019 WL 5884466, at *4 (S.D.N.Y. Nov. 12, 2019), the court held that an expert witness was qualified to testify because "[a]lthough [the physician] is not an orthopedist, the fields of radiology and orthopedics are closely related."

In this case, Dr. Lind may be qualified in obstetrics, gynecology, female pelvic medicine, and reconstructive surgery; however, beyond medical school he has no education, training, or experience in mental health diagnosis and treatment, he has no licenses or certifications related to mental health, and he has identified no instance in which he diagnosed or treated a patient's mental health impairments. *See Est. of Jaquez by Pub. Adm'r of Bronx Cnty. v. City of New York*, 706 F. App'x 709, 716 (2d Cir. 2017) (upholding a district court ruling excluding expert testimony by a physician regarding a person's "psychological state" because he specialized in emergency medicine and "was not shown to have expertise in psychiatric diagnosis"); *Balura*, 2020 WL 819293, at *5 (observing that "the court must ensure that the expert will testify on subjects that are within her or his area of expertise"); *Bah v. City of New York*, 2017 WL 435823, at *10 (S.D.N.Y. Jan. 31, 2017) (excluding an expert's testimony about a plaintiff's "psychological state[]" because although he "appear[ed] to be an extraordinarily well qualified forensic pathologist and medical examiner[,] . . . it is not immediately clear to the Court how these occupations involve an expertise in psychiatry"); *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 723-24 (7th Cir. 1999) (holding that a district court erred in permitting a witness with expertise in metal science and metallurgy to testify about the effects of welding fumes on the body). Although a lack of specialization will not always preclude an expert from testifying, obstetrics and gynecology are not closely related to the field of mental health, and Dr. Lind has demonstrated no skill, education, or expertise in the latter discipline that will be helpful to the jury. *See Fed. R. Evid. 702.*

As a further ground for inadmissibility, Dr. Lind's opinion apparently contains nothing more than a chronology of Plaintiff J. Leavitt's mental health history juxtaposed with the dates of her TVT implantation and the complications that arose thereafter. An expert witness must offer more than a mere conduit for a party's or witness's testimony. *See SourceOne Dental, Inc. v. Patterson Cos.*, 2018 WL 2172667, at *7 (E.D.N.Y. May 10, 2018) ("Expert testimony is not admissible if it merely serves as a conduit to construct a factual narrative" because such testimony will not be helpful to the finder of fact) (citing *Highland Cap. Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005)); *see also Rotman v. Progressive Ins. Co.*, 955 F. Supp. 2d 272, 283 (D. Vt. 2013) (observing that "[t]o the extent [an expert witness] merely repeats or recasts the testimony of [a fact witness] in order to arrive at a theory of causation, he is not testifying as an expert witness based upon specialized knowledge, but rather is acting as a conduit for another witness's testimony in the guise of an expert's opinion"). A jury is capable of understanding that Plaintiff J. Leavitt's history of mental health predates her TVT implantation and resulting complications and making its own inferences from the chronology of events. Expert witness testimony is not needed for that purpose. Accordingly, Plaintiffs' motion to exclude Dr. Lind's testimony regarding Plaintiff J. Leavitt's mental health is GRANTED.

CONCLUSION

For the foregoing reasons, Defendants' motion to exclude opinions and certain testimony of Dr. Ostergard is GRANTED. (Doc. 30.) Plaintiffs' motion to exclude opinions and certain testimony of Dr. Lind is GRANTED. (Doc. 32.)
SO ORDERED.

Dated at Burlington, in the District of Vermont, this 19th day of August, 2021.



Christina Reiss, District Judge
United States District Court